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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/308,219	09/19/1994	MARC ALIZON	3495.001020	4832

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FINNEGAN, HENDERSON, FARABOW, GARRETT &  
DUNNER LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/16/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/308,219

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 May 1995.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status*

1. This rejection is non-final. It is noted that this application was suspended pending the result of Interference 102,822, which interference was resolved in favor of the other party. Therefore, the Chang et al patent, cited below in the 102 rejections, is properly 102(e) art which cannot be rebutted due to res judicata.
2. Separately, Applicant is requested, in any response to this office action, to submit a copy of the original claims which were submitted for interference, in order to determine which claims, if any, should be cancelled under 37 CFR 1.663.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 11, 13, 15, 17, 19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Art Unit: 1637

The claims utilize the open "having" language which permits the inclusion of additional elements. "Having" is interpreted as being of identical scope to "comprising".

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NOs: 3 and 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (see figure 3).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the regions claimed are presented below.

## Alignment

```

                                     gggggactggaagggctaa 8654
                                     |||||
                                     gggggactggaagggctaa 8453

Query: 8655  ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714
           |||||
Sbjct: 8454  ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513

Query: 8715  tccctgattggcagaactacacaccagggccagggtcagatatccactgacctttggat 8774
           |||||
Sbjct: 8514  tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573

Query: 8775  ggtgctacaagctagtaggtgagccagataaggtagaagaggccaataaaggagaga 8834
           |||||
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Art Unit: 1637

Sbjct: 8574 ggtgctacaagctagtagaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633

Query: 8835 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccctgagagagaagtgt 8894

|||||

Sbjct: 8634 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccggagagagaagtgt 8693

Query: 8895 tagagtggaggtttgacagccgcttagcatttcacacgtggcccgagagctgcatccgg 8954

|||||

Sbjct: 8694 tagagtggaggtttgacagccgcttagcatttcacacgtggcccgagagctgcatccgg 8753

Query: 8955 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 9014

|||||

Sbjct: 8754 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 8813

Query: 9015 cagggaggcgtggcctggcgggactggggagtggcgagccctcagatgctgcatataa 9074

|||||

Sbjct: 8814 cagggaggcgtggcctggcgggactggggagtggcgagccctcagatcctgcatataag 8873

Query: 9075 cagctgctttttgcctgtactgggtctctctggttagaccagatttgagcctgggagctc 9134

|||||

Sbjct: 8874 cagctgctttttgcctgtactgggtctctctggttagaccagatctgagcctgggagctc

Query: 39 tctggctaactaggaacccactgcttaagcctcaataaagcttgcccttgagtgccttcaa 98

|||||

Sbjct: 1 tctggctaactaggaacccactgcttaagcctcaataaagcttgcccttgagtgccttcaa 60

Query: 99 gtagtgtgtgcccgtctgtgtgtgactctggtaactagagatccctcagacccttttag 158

|||||

Sbjct: 61 gtagtgtgtgcccgtctgtgtgtgactctggtaactagagatccctcagacccttttag 120

Query: 159 tcagtgtggaatactcttagcagtggcgcccgaacagggacttgaaagcgaaagggaaan 218

|||||

Sbjct: 121 tcagtgtggaatactcttagcagtggcgcccgaacagggacctgaaagcgaaagggaaac 180

Query: 219 ca 220

||

Sbjct: 181 ca 182

It is noted that with regard to, for example, the sequence region that is disclosed has 12 nucleotide differences in a sequence of 695 nucleotides. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as

Art Unit: 1637

evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 695 nucleotide sequence which is the first sequence of claim 11, twelve errors would represent approximately a 1.7% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper. With regard to the terminal sequence, it is noted that the Chang reference teaches lambda clones comprising the HTLV-III DNA which would comprise the entire claimed sequence (column 6, lines 50-58).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Art Unit: 1637

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 11 under 102(e) as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 11 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Chang because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the

Art Unit: 1637


samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White to detect HIV as taught by Chang since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

May 15, 2002